

Message Text

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PAGE 01 STATE 268659

14

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DRAFTED BY: DHEW/FDA: WJKUSTKA:AMS

APPROVED BY: OES/APT/BMP: MBEAUBIEN

DHEW/OIH: MACODDING

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FM SECSTATE WASHDC

TO AMEMBASSY MOSCOW

UNCLAS STATE 268659

E.O. 11652: N/A

TAGS: OGEN, OTRA, TBIO, UR

SUBJECT: VISIT OF FDA REPRESENTATIVE

REF: MOSCOW 15785, STATE 258814

1. THE PROPOSED VISIT OF MR. MCDERMAID OF FDA TO MEDEXPORT HAS BEEN CANCELLED AT THIS TIME.

2. AS BACKGROUND: MEDEXPORT MANUFACTURES A PRODUCT WHICH IS THE SUBJECT OF A NEW DRUG APPLICATION BY THE LANNETT CO., INC., PHILADELPHIA. THE PRODUCT IS IMPORTED FOR THE LANNETT CO., INC. BY GYMA LABS. FDA CANNOT MAKE A DECISION ON APPROVAL OF NEW DRUG APPLICATION UNTIL FACTORY VISIT ASSURES THAT MEDEXPORT IS CAPABLE OR PRODUCING THE DRUG IN CONFORMANCE WITH CURRENT GOOD MANUFACTURING PRACTICES. MR. RALF LIPTON OF GYMA LABS HAD MADE PRELIMINARY ARRANGEMENTS THROUGH MR. B. M. LEVIN OF MEDEXPORT. ON 11-5-75, MR. LEVIN REPORTED TO MR. LIPTON THAT HE DID NOT HAVE AUTHORITY TO MAKE A DECISION FOR FDA VISIT TO MEDEXPORT.

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3. MEDEXPORT AND GYMA LABS CONTEMPLATE SCHEDULING THE TRIP LATER

AFTER ARRANGEMENTS CAN BE MADE THROUGH PROPER RUSSION AGENCIES.
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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
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Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
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Disposition Authority: n/a
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Margaret P. Grafeld
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